



RESPONSE TO THE PROPOSED  
INCLUSION OF  
ULTRAVIOLET RADIATION  
(UVR)  
AS A CARCINOGEN

In The

**Tenth Annual Report on Carcinogens**

Submitted By  
Donald L. Smith

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**SECTION 1.0**

**INTRODUCTION**

Submitted By

Donald L. Smith



## **ULTRAVIOLET MEDICAL SYSTEMS**

Division Of Reykdal-Smith Enterprises, LLC

1862 W. Shoal Creek Lane / Tucson, AZ 85737  
(520) 797-0764 / (520) 323-9127 (Fax)  
Reyksmith@AOL.com

June 3, 1999

Dr. C. W. Jameson  
NIEHS / Building 4401/ Room 3127 / MD: EC-14  
79 Alexander Drive  
Research Triangle Park, NC 27709

Dear Dr. Jameson:

Enclosed you will find one (1) master copy and six (6) copies of my: "Response To The Proposed Inclusion Of Ultraviolet Radiation (UVR) As A Carcinogen" in the *Tenth Annual Report on Carcinogens*.

Please let me know if you require additional information.

I would like to receive copies of all responses made by other parties.

I would like to inform you of the fact that I am a member of the Salon Advisory Panel of the International Smart Tan Network whose Executive Director is Joseph A. Levy. I have sent him copies of this response and have given him permission to use any and all material that he chooses to use in his submission. Therefore, if my material and his appears to be similar or identical, there is a valid reason for it. We had a very limited amount of time to prepare our submissions and we did not have time to merge them into one document.

Thank you for your cooperation.

Sincerely,

Donald L. Smith  
President

**SECTION 2.0**

**EXECUTIVE SUMMARY**

Submitted By

Donald L. Smith

## 2.0 **EXECUTIVE SUMMARY**

### 2.1 **Position Statement**

It is the position of Donald L. Smith (DLS), that **neither** the specific wavelengths that make up **UV-B** radiation (280 - 315 nm) **nor** the specific wavelengths that make up **UV-A** radiation (315 - 400 nm), referred to collectively as "ultraviolet radiation" (UVR), **should be listed as a carcinogen** in the *Tenth Annual Report on Carcinogens*.

DLS does not have a position regarding UV-C because those wavelengths are not utilized by the indoor tanning industry.

### 2.2 **Conditions For Listing UVR Radiation As A Carcinogen**

It will be scientifically inaccurate and misleading to the American public to list UVR as a carcinogen **unless and until** the following conditions are met:

2.21 **Specification of UVR Component.** It is scientifically inaccurate and misleading to the American public to say, state or imply that UVR (ultraviolet radiation) is a carcinogen without specifying the component of UVR that is alleged to be carcinogenic. This claim must be supported by unambiguous human data that provides conclusive proof that the specific component of UVR claimed to be carcinogenic is, in fact, a carcinogen.

2.22 **Specification of Source of UVR.** It is scientifically inaccurate and misleading to the American public to say, state or imply that a component of UVR is a carcinogen without specifying **the source** of the specific component of UVR that is claimed to be a carcinogen. This claim must quantitate the Relative Risk that an individual has accumulated by virtue of exposure to UVR for (at least) the following sources of UVR: (1) sunlight, (2) tanning lamps used by an individual in commercial tanning salons, (3) tanning lamps used by an individual in home tanning units, (4) environmental sources, and, (5) medical uses.

### 2.3 **Conditions For Listing UV-B Radiation As A Carcinogen**

2.31 **Specification of Type of Skin Cancer.** It is scientifically inaccurate and misleading to the American public to say, state or imply that "skin cancer" is caused (or induced) by UV-B radiation, from a specific source, without stating the **specific form of skin cancer** that is caused (or induced) by UV-B. This claim must be supported by unambiguous human data that provides conclusive proof of UV-B's involvement as a carcinogen.  
(See Sections 6.0 and 7.0)

2.32 **Specification of Phototypes / Subtypes.** It is scientifically inaccurate and misleading to the American public to say, state or imply that the specific form of skin cancer being discussed is **applicable to all skin phototypes / subtypes**. The specific phototype / subtype involved with a specific form of skin cancer being discussed must be listed and supported by unambiguous human data that provides conclusive proof of UV-B's involvement as a carcinogen for that phototype / subtype.  
(See Section 9.0)

2.33 Specification of Sensitivity /Tolerance Levels. It is scientifically inaccurate and misleading to the American public to say, state or imply that the specific form of skin cancer being discussed that is caused by a specific component of UVR, from a specific source, and applicable to the specific phototype / subtype described, is applicable to all levels of UVR sensitivity (SUVR) and tolerance (TUVR). The specific sensitivity or tolerance level that is applicable for the specific form of skin cancer being discussed for the specific phototype / subtype involved must be listed and supported by unambiguous human data that provides conclusive proof of UV-B's involvement as a carcinogen. (See Section 8.0)

2.34 Cocarcinogen Involvement. It is scientifically inaccurate and misleading to the American public to say, state or imply that UV-B, from a specific source, is a carcinogen if the means by which UV-B causes (or induces) a specific form of skin cancer is by the concurrent action of a cocarcinogen or by the concerted action of cocarcinogens. In addition, the relative contribution of each specific cocarcinogen toward the cause (or induction) of the specific form of skin cancer being discussed must be listed and supported by unambiguous human data that provides conclusive proof of UV-B's involvement as a carcinogen. (See Section 5.0)

2.35 Role of Temperature. Data has been provided in this submission (Section 6.0) supporting the theory that temperature is the primary climactic factor that causes (or induces) melanoma skin cancer and may be a major or minor contributor to the cause (or induction) of Basal Cell Carcinoma and Squamous Cell Carcinoma. It will be scientifically inaccurate and misleading to the American public to say, state or imply that UV-B causes (or induces) a specific form of skin cancer, in a specific phototype / subtype, at a specific sensitivity / tolerance level, in the presence or absence of a cocarcinogen or cocarcinogens, unless and until there is unambiguous human data that rules out the involvement of temperature as a carcinogen or cocarcinogen. (See Section 6.0)

2.36 Economic Impact. It is required that an assessment of the specific economic impact that listing UV-B, from a specific source, as the cause (or inducing agent) of a specific form of skin cancer, in a specific phototype / subtype, at a specific sensitivity / tolerance level, after ruling out the possible involvement of temperature and the presence or absence of a carcinogen(s), would have on the indoor tanning industry.

Because DLS does not believe that the National Institute of Environmental Health Sciences / NTP and/or the National Institutes of Health have the requisite knowledge of the indoor tanning industry to conduct a thorough economic impact assessment, DLS requests that he be allowed to take part in the design of the study, the study itself, and the preparation of the economic impact assessment report.

2.37 Paperwork Impact. It is required that an assessment of the specific paperwork impact that listing UV-B, from a specific source, as the cause (or inducing agent) of a specific form of skin cancer, in a specific phototype / subtype, at a specific sensitivity / tolerance level, after ruling out the possible involvement of temperature and the presence or absence of a cocarcinogen(s), would have on the indoor tanning industry.

Because DLS does not believe that the National Institute of Environmental Health Sciences / NTP and/or National Institutes of Health has the requisite knowledge of the indoor tanning industry to conduct a thorough paperwork impact assessment, DLS requests that he be allowed to take part in the design of the study, the study itself, and the preparation of the paperwork impact assessment report.

2.38 Health Impact on American Public. DLS believes that there will be a significant adverse health impact on the American public if UV-B, from a specific source, is listed as the cause (or inducing agent) of a specific form of skin cancer, in a specific phototype / subtype, at a specific sensitivity / tolerance level, after ruling out the possible involvement of temperature and the presence or absence of a cocarcinogen(s).

DLS, therefore, requests that an assessment of the potential adverse health impact on the American public be made before listing UV-B as the cause (or inducing agent) of a specific form of skin cancer, in a specific phototype / subtype, at a specific sensitivity / tolerance level, after ruling out the possible involvement of temperature and the presence or absence of a cocarcinogen(s).

#### **2.4 Conditions For Listing UV-A Radiation As A Carcinogen**

2.41 Specification of Type of Skin Cancer. It is scientifically inaccurate and misleading to the American public to say, state or imply that "skin cancer" is caused (or induced) by UV-A radiation, from a specific source, without stating the specific form of skin cancer that is caused (or induced) by UV-A. This claim must be supported by unambiguous human data that provides conclusive proof of UV-A's involvement as a carcinogen. (See Sections 6.0 and 7.0)

2.42 Specification of Phototypes / Subtypes. It is scientifically inaccurate and misleading to the American public to say, state or imply that the specific form of skin cancer being discussed is applicable to all skin phototypes / subtypes. The specific phototype / subtype involved with a specific form of skin cancer being discussed must be listed and supported by unambiguous human data that provides conclusive proof of UV-A's involvement as a carcinogen for that phototype / subtype. (See Section 9.0)

2.43 Specification of Sensitivity /Tolerance Levels. It is scientifically inaccurate and misleading to the American public to say, state or imply that the specific form of skin cancer being discussed that is caused by a specific component of UVR, from a specific source, is applicable to the specific phototype / subtype described, is applicable to all levels of UVR sensitivity (SUVR) and tolerance (TUVR). The specific sensitivity or tolerance level that is applicable for the specific form of skin cancer being discussed for the specific phototype / subtype involved must be listed and supported by unambiguous human data that provides conclusive proof of UV-A's involvement as a carcinogen. (See Section 8.0)

2.44 Cocarcinogen Involvement. It is scientifically inaccurate and misleading to the American public to say, state or imply that UV-A, from a specific source, is a carcinogen if the means by which UV-A causes (or induces) a specific form of skin cancer is by the concurrent action of a cocarcinogen or by the concerted action of cocarcinogens. In addition, the relative contribution of each specific cocarcinogen toward the cause (or induction) of the specific form of skin cancer being discussed must be listed and supported by unambiguous human data that provides conclusive proof of UV-B's involvement as a carcinogen. (See Section 5.0)

2.45 Role of Temperature. Data has been provided in this submission (Section 6.) supporting the theory that temperature is the primary climactic factor that causes (or induces) melanoma skin cancer and may be a major or minor contributor to the cause (or induction) of Basal Cell Carcinoma and Squamous Cell Carcinoma. It will be scientifically inaccurate and misleading to the American public to say, state or imply that UV-A causes (or induces) a specific form of skin cancer, in a specific phototype / subtype, at a specific sensitivity / tolerance level, in the presence or absence of a cocarcinogen or cocarcinogens, unless and until there is unambiguous human data that rules out the involvement of temperature as a carcinogen or cocarcinogen. (See Section 6.0)

2.46 Economic Impact. It is required that an assessment of the specific economic impact that listing UV-A, from a specific source, as the cause (or inducing agent) of a specific form of skin cancer, in a specific phototype / subtype, at a specific sensitivity / tolerance level, after ruling out the possible involvement of temperature and the presence or absence of a carcinogen(s), would have on the indoor tanning industry.

Because DLS does not believe that the National Institute of Environmental Health Sciences / NTP and/or the National Institutes of Health have the requisite knowledge of the indoor tanning industry to conduct a thorough economic impact assessment, DLS requests that he be allowed to take part in the design of the study, the study itself, and the preparation of the economic impact assessment report.

2.47 Paperwork Impact. It is required that an assessment of the specific paperwork impact that listing UV-A, from a specific source, as the cause (or inducing agent) of a specific form of skin cancer, in a specific phototype / subtype, at a specific sensitivity / tolerance level, after ruling out the possible involvement of temperature and the presence or absence of a cocarcinogen(s), would have on the indoor tanning industry.

Because DLs does not believe that the National Institute of Environmental Health Sciences / NTP and/or National Institutes of Health has the requisite knowledge of the indoor tanning industry to conduct a thorough paperwork impact assessment, DLS requests that he be allowed to take part in the design of the study, the study itself, and the preparation of the paperwork impact assessment report.

2.48 Health Impact on American Public. DLS believes that there will be a significant adverse health impact on the American public if UV-A, from a specific source, is listed as the cause (or inducing agent) of a specific form of skin cancer, in a specific phototype / subtype, at a specific sensitivity / tolerance level, after ruling out the possible involvement of temperature and the presence or absence of a cocarcinogen(s).

DLS, therefore, requests that an assessment of the potential adverse health impact on the American public be made before listing UV-A, from a specific source, as the cause (or inducing agent) of a specific form of skin cancer, in a specific phototype / subtype, at a specific sensitivity / tolerance level, after ruling out the possible involvement of temperature and the presence or absence of a cocarcinogen(s).

## 2.5 Consequences Of Listing UVR Aa A Carcinogen

2.51 The American Public. As mentioned previously in Section 2.48, DLS believes that there will be a significant adverse health impact on the American public if UVR is listed as a carcinogen in the *Tenth Annual Report on Carcinogens* because millions of citizens who are currently practicing sensible, moderate, appropriate and responsible tanning, will practice avoidance of the sun and will not patronize indoor tanning salons. This UVR avoidance will lead to (1) an increase in erythema (sunburn) because of the resultant lack of facultative pigmentation, (2) a possible increase in the incidence and mortality of certain forms of skin cancer because of the increase of erythema (sunburn), and, (3) an increase in the number of American citizens who have sub-optimal, insufficient or deficient levels of vitamin D which will accentuate the "silent epidemic" of this condition that adversely affects the American public.

Furthermore, should dermatologists "control" the administration of UVR (See Section 2.55), those individuals who choose to tan (after all, tanning is an adult activity, freely chosen), will pay double or triple the prices currently being charged by the indoor tanning industry.

Is one objective of listing UVR as a carcinogen to adversely impact the health of the American public? Is another objective of listing UVR as a carcinogen to increase the fees paid by consumers?

2.52 The Indoor Tanning Industry. Within three years after the listing of UVR as a carcinogen in the *Tenth Annual Report on Carcinogens*, ISTN believes that 20-30% of the existing indoor tanning salons in the United States will be forced to go out of business, causing a \$500 million dollar loss to the American economy.

Is one objective of listing UVR as a carcinogen to decimate the indoor tanning industry?

2.53 The Sunscreen Industry. The sunscreen industry, on the other hand, will see a substantial increase in their business as more Americans are convinced that sunlight is harmful to them because of listing UVR as a carcinogen. This is troubling since there are an increasing number of scientific reports being published that question this practice. After all, a sunscreen attempts to artificially "mimic" the known photo-protective and thermo-protective benefits of acquired facultative pigmentation, which is better known as a "tan".

Is one objective of listing UVR as a carcinogen to stimulate the sunscreen industry?

2.54 The Vitamin D Industry. The vitamin D industry will also see a substantial increase in business since many Americans will be afraid to utilize either sunlight or an indoor tanning bed to produce (cutaneously) vitamin D and there will be no alternative to vitamin D supplementation. Since supplemental forms of vitamin D are expensive, are not as biologically active and have a risk of toxicity, this alternative is not without cost or risk.

Is one objective of listing UVR as a carcinogen to stimulate the vitamin D industry?

2.55 The American Academy of Dermatology (AAD). The AAD will have won a major victory over the indoor tanning industry and will, therefore, be able to "control" the provision of UVR. Should American dermatologists then offer the development of facultative pigmentation (a "tan") under their control and direction, they (the AAD) will have, in essence, been granted an unsupervised monopoly. Unsupervised because what a medical professional does under the provisions of his license is not subject to state or federal regulatory control.

Is one objective of listing UVR as a carcinogen to grant American dermatologists an unsupervised monopoly to provide UVR?

2.56 Please See Section 3.0 - Qui Bono? Who Profits From This?

DLS recommends that especial attention be paid to the comments made in Section 3.0 - Qui Bono? Who Profits From This?

## **2.6 Decision Tree.**

DLS also recommends that the Decision Tree provided in Section 2.0 (Page 2-7-6/1) be used as a template for ascertaining whether or not UVR, or UV-B, or UV-A should be listed as a carcinogen in the *Tenth Annual Report on Carcinogens*.

## DECISION TREE

### Is UVR, or UV-B, or UV-A A Carcinogen That Should Be Listed In The Tenth Annual Report on Carcinogens

- Step 1: Is UVR a carcinogen?  
a. Yes  
b. No
- Step 2: If yes, for what specific component of UVR?  
a. UV-B  
b. UV-A
- Step 3: What is the source of the specific component of UVR identified as a carcinogen in Steps 1 and 2?  
a. Sunlight?  
b. Commercial tanning bed?  
c. Home tanning bed?  
d. Environmental sources?  
e. Medical sources?
- Step 4: What is the Relative Risk conveyed by the source (or sources) identified in Steps 1, 2 and 3?
- Step 5: What is the specific form of skin cancer that has been caused (or induced) by Steps 1, 2, 3 and 4?
- Step 6: What phototypes / subtypes are affected by Steps 1, 2, 3, 4 and 5?
- Step 7: What sensitivity to UVR (SUVR) and tolerance to UVR (TUVR) levels are applicable to Steps 1, 2, 3, 4, 5, and 6?
- Step 8: Is a cocarcinogen or cocarcinogens involved in Steps 1, 2, 3, 4, 5, 6 and 7?
- Step 9: If the answer to Step 8 is Yes, state the Relative Contribution of each cocarcinogen to Steps 1, 2, 3, 4, 5, 6, 7 and 8?
- Step 10: Is temperature the primary climactic factor involved in Steps 1, 2, 3, 4, 5, 6, 7, 8 and 9? If Yes, please quantitate.
- Step 11: Is temperature a secondary climactic factor involved in Steps 1, 2, 3, 4, 5, 6, 7, 8, and 9? If Yes, please quantitate.
- Step 12: What is the economic impact to the indoor tanning industry if UVR, or UV-B, or UV-A are listed as carcinogens in the Tenth Annual Report on Carcinogens?
- Step 13: What is the paperwork impact to the indoor tanning industry if UVR, or UV-B, or UV-A are listed as carcinogens in the Tenth Annual Report on Carcinogens?
- Step 14: What is the health impact on the American public if UVR, or UV-B, or UV-A are listed as carcinogens in the Tenth Annual Report on Carcinogens?

(2-7-6/1)